

Applicants: Robert J. Winchester, et al.
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REMARKS

Claims 18 and 19 are pending and under examination. Claims 1-6, 8-10, and 13-15 have been canceled without prejudice as having been withdrawn. Thus, claims 18 and 19 will remain pending and under examination upon entry of this Amendment.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the March 11, 2004 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

The Claimed Invention

This invention provides a composition comprising (a) an effective amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, wherein the composition is indicated for treating rheumatoid arthritis.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 18 and 19 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Specifically, the Examiner alleged that claim 18 is indefinite in the recitation of "indicated for treating rheumatoid arthritis" because it is unclear if this clause refers to an intended use or a label or instruction supplied with the composition that communicates this intended use.

In response, applicants maintain that the phrase "indicated for treating rheumatoid arthritis" could have no meaning to one of

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skill in the art other than a label or instruction, supplied with the composition, setting forth such indication.

In support of this rejection, the Examiner makes two statements. First the Examiner asserts that "virtually no prescription drug has a label which indicates an intended use." Second, the Examiner asserts that "use of common drugs for 'off use' purposes is also found wherein the label or instructions do not communicate a common use."

In response, applicants respectfully disagree with the Examiner's first assertion, noting that FDA rules require that all drugs, prescription or otherwise, be accompanied by a manufacturer's label or instructions setting forth the drug's indication. The fact that such labels may or may not accompany the drug when distributed by a pharmacy to an end user does not negate the FDA's requirements of manufacturers. Also, regardless of whether a manufacturer's original label remains with a drug, the end user, in the case of a prescription drug, could only receive the drug accompanied by the doctor's oral or written instructions to use it for its intended purpose.

Moreover, applicants stress that the issue here is whether the claims define the metes and bounds of the invention. Applicants maintain that they do, and that the veracity of the Examiner's remarks regarding drug labeling and off-label use is inapposite to the rejection at hand.

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §112, second paragraph.

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Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 18 and 19 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner alleged that the specification lacks support for the clause "indicated for treating rheumatoid arthritis" in claim 18. The Examiner asserted that the reference in the specification to a "composition for treating rheumatoid arthritis" indicates an intended use, not that the composition has a label or instructions for treating rheumatoid arthritis. The Examiner also stated that to the extent that the clause "indicated for treating rheumatoid arthritis" indicates anything other than an intended use, it constitutes new matter.

In response, applicants respectfully traverse. Applicants note that the language "composition for treating rheumatoid arthritis" is found, *inter alia*, at page 10, lines 9 and 10, of the specification. Applicants maintain that the phrase "composition for treating rheumatoid arthritis," read in the context of the instant specification, indicates that (a) the composition has a specific use for treating rheumatoid arthritis, and (b) this specific use would necessarily be manifested by a label or instructions indicating such use. Applicants are thus unaware of how the claims as presently worded raise the issue of new matter.

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §112, first paragraph.

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Rejection Under 35 U.S.C. §102(a)

The Examiner rejected claims 18 and 19 under 35 U.S.C. §102(a) as allegedly anticipated by Schols, et al. (1997). Specifically, the Examiner stated that the recitation of an intended use carries no patentable weight in the instant product claims.

In response, applicants respectfully traverse.

In order to anticipate the instant claims, Schols must teach each and every aspect thereof. Schols does not meet this requirement. Specifically, Schols fails to teach a composition comprising a bicylciam *indicated for the treatment of rheumatoid arthritis*.

Applicants maintain that the clause "indicated for treating rheumatoid arthritis" would necessarily mean the provision of instructions or a label directing the composition's use for the treatment of rheumatoid arthritis. The provision of these instructions or label is not taught in Schols, and therefore this clause adequately distinguishes the claims over the prior art.

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §102(a).

Rejections Under 35 U.S.C. §102(b)

The Examiner rejected claims 18 and 19 under 35 U.S.C. §102(b) as allegedly anticipated by De Vreese, et al. (1996), as evidenced by Schols et al. Specifically, the Examiner stated that the recitation of an intended use carries no patentable weight in the instant product claims.

In response, applicants respectfully traverse for the reasons set forth above in connection with the Examiner's rejection under 35

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U.S.C. §102(a).

The Examiner also rejected claim 18 under 35 U.S.C. §102(b) as allegedly anticipated by Murrer, et al. (U.S. Patent No. 5,021,409) and also by Datema et al. as evidenced by Schols.

In response, applicants respectfully traverse and maintain that since neither Murrer nor Datema teaches the element of an indication for treating rheumatoid arthritis using a bicyclam composition, neither Murrer nor Datema anticipates the claimed invention.

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §102(b).

Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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